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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,382	04/20/2001	Harry D. Danforth	0100.00	9258
25295	7590	06/15/2004	EXAMINER	
USDA, ARS, OTT 5601 SUNNYSIDE AVE RM 4-1159 BELTSVILLE, MD 20705-5131			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/838,382	Applicant(s) DANFORTH ET AL.	
	Examiner Ja-Na Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-16 is/are pending in the application.
- 4a) Of the above claim(s) 3-13 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-15 is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 12, 2004 has been entered.

Amendment Entry

2. The amendments filed February 13, 2004 and April 12, 2004 have been entered. The examiner acknowledges the amendment to the specification. Claims 1-2 have been cancelled. Claims 3-13 have been withdrawn. Claims 14-16 have been newly added.
3. A complete reply to the rejection must include cancellation of nonelected and withdrawn claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Withdrawal of Rejections

4. The following rejections have been withdrawn in view of applicants' amendments and arguments:
- a) The deposit rejection of claims 1-2 under 35 U.S.C. 112, first paragraph;
 - b) The rejection of claims 1-2 under 35 U.S.C. 112, second paragraph;

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c) The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Barta et al; and

d) The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Martin et al.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 16 is dependent ultimately upon claim 14, the claim is drawn to a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in claim 15 wherein: immunization with said variant strain or *E. maxima* -I (ATCCC number PTA-4959) protects against challenge with said variant strain or *E. maxima*-I (ATCC number PTA-4959), but does not protect against challenge with *E. maxima*-GLP, an indication that said variant strain has no detectable immunological cross reactivity with *E. maxima*-GLP.

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The written description in this case only sets forth the strain *E. maxima*-I ATCC number PTA-4959 as having the characteristic that upon immunization with *E. maxima* -I (ATCCC number PTA-4959) the strain protects against challenge with *E. maxima*-I (ATCC number PTA-4959), but does not protect against challenge with *E. maxima*-GLP, as an indication that said variant strain has no detectable immunological cross reactivity with *E. maxima*-GLP, therefore the written description is not commensurate in scope with the claim drawn to a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959). Neither the specification nor the claims teach the identity of a variant strain that is not ATCC-PTA 4959 yet corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959). Thus applicants were not in possession of a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959). The specification does not include structural examples of a variant that has corresponding characteristics to the strain *E. maxima*-I (ATCC number PTA-4959). Thus, the resulting variant strain could result in a strain not taught and enabled by the specification.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Example 6 of the instant specification only teaches that strain ATCC PTA-4959 has the characteristic that upon immunization with *E. maxima* -I (ATCCC number PTA-4959) the strain protects against challenge with *E. maxima*-I (ATCC number PTA-4959),

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but does not protect against challenge with *E. maxima*-GLP, as an indication that said variant strain has no detectable immunological cross reactivity with *E. maxima*-GLP. The example and specification state that the other strains tested by applicants' such as the MSS strain failed to have the required characteristics. Moreover, applicants' state that other strains known in the art such the strains disclosed by Martin et al., and Barta et al., fail to have the requisite corresponding characteristics. Moreover, pages 8, 14-16 and 18 of the instant specification fail to disclose a variant strain that corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) wherein immunization with said variant strain or *E. maxima* -I (ATCCC number PTA-4959) protects against challenge with said variant strain or *E. maxima*-I (ATCC number PTA-4959), but does not protect against challenge with *E. maxima*-GLP, an indication that said variant strain has no detectable immunological cross reactivity with *E. maxima*-GLP. Thus, there is evidence that other variant strains known in the art do not have the required characteristics. There is no teaching in the specification that discloses the identity of a variant strain that has the claimed characteristics to thereby indicate that said variant strain has no detectable immunological cross reactivity with *E. maxima*-GLP. In view of the lack of evidence, it is apparent that Applicants' were not in possession of additional variant strains, at the time of filing the instant application such as a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in claim 15 wherein: immunization with said variant strain or *E. maxima* -I (ATCCC number PTA-4959) protects against challenge with said variant strain or *E. maxima*-I (ATCC number PTA-4959), but does not protect against challenge with *E. maxima*-GLP, an indication that said variant strain has no detectable immunological cross reactivity with *E. maxima*-GLP.

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With the exception of deposited *E. maxima-I* variant strain identified as ATCC number PTA-4959, the skilled artisan cannot envision the detailed structure of the isolated variant strain, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention. The bacterium itself, or a nucleic acid structure is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. The immunization characteristics and non-cross-reactivity abilities distinguish the claimed variant strain only by what it does, i.e., by immunization and lack of cross-reactivity, which are purely functional distinctions. Even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. The instant specification and claims describe a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima-I* (ATCC number PTA-4959) by its function i.e., immunization and cross-reactivity abilities, however this description does not describe the claimed variant strain itself, nor does it provide the identity of the strain.

See also, *In The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), where the court held that a generic statement that defines a genus of nucleic acids by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the

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recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Thus, in the absence of the identity of the variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959), a variant strain described only by its ability to immunize and not be cross reactive fails to meet the written description requirements. Therefore only the variant strain deposited as ATCC number PTA-4959, and not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph.

6. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in claim 15 wherein: immunization with said variant strain or *E. maxima* -I (ATCCC number PTA-4959) protects against challenge with said variant strain or *E. maxima*-I (ATCC number PTA-4959), but does not protect against challenge with *E. maxima*-GLP, an indication that said variant strain has no detectable immunological cross reactivity with *E. maxima*-GLP.

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Applicant failed to point to support in the specification for a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in claim 15. Moreover, applicant failed to specifically point to the identity of a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in claim 15 wherein the corresponding characteristic is that upon immunization with said variant strain or *E. maxima* -I (ATCCC number PTA-4959) protects against challenge with said variant strain or *E. maxima*-I (ATCC number PTA-4959), but does not protect against challenge with *E. maxima*-GLP, an indication that said variant strain has no detectable immunological cross reactivity with *E. maxima*-GLP. Thus, there appears to be no teaching of a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in claim 15. Applicant has pointed to pages 8, 14-16 and 18 of the instant specification for support of the amendment which is drawn to the variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in claim 15, however it appears that the entire specification appears to fail to recite support for the newly recited variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959). At the pointed to pages, the specification teaches the abilities of strain PTA-4959. There is no teaching of another variant strain of *Eimeria maxima* that is defined by the characteristic wherein upon immunization with said variant strain or *E. maxima* -I (ATCCC number PTA-4959)

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protects against challenge with said variant strain or *E. maxima*-I (ATCC number PTA-4959), but does not protect against challenge with *E. maxima*-GLP, as an indication that said variant strain has no detectable immunological cross reactivity with *E. maxima*-GLP.

It is noted that the examples in the specification fail to disclose the identity of a variant strain that is not the deposited strain ATCC PTA-4959 having the claimed characteristics. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity of a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as recited by the newly added claim. Therefore, the new claim incorporates new matter and is accordingly rejected.

Allowable Subject Matter

7. Claims 14-15 are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines *ja*
June 9, 2004

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